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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES, AND
TOXIC SUBSTANCES

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MEMORANDUM

June 30, 2009

SUBJECT: **Saflufenacil (BAS 800 H):** Transmittal of Ecological Effects Data Evaluation Reviews (DERs)

TO: Kathryn Montague, Product Manager
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APease 6/30/09

THROUGH: Elizabeth Behl, Branch Chief
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M. Schemenic (for E. Behl) 6/30/09

The Environmental Fate and Effects Division (EFED) has completed its review of 45 ecotoxicity studies submitted to support the registration of the new herbicide, saflufenacil, for the proposed uses on cereal small grains, corn, chickpeas, cotton, edible beans, edible peas, lentils, lupine, sorghum, soybeans, sunflowers, fruit tree orchards, nut tree orchards, vineyards, fallow croplands, and non-agricultural areas including pine plantations, rights-of-way, bare ground, and Christmas tree plantations. Ecological effects data were submitted for technical grade saflufenacil (BAS 800 H), formulated products (BAS 781 02H, BAS 800 01H, and BAS 800 02H), and degradates (M07 and M08). Official signed copies of the DERs accompany this memo.

Of the 45 submitted studies, 37 are classified as "Acceptable" and eight are classified as "Supplemental". Seven of the eight studies classified as "Supplemental" were non-guideline studies. The remaining "Supplemental" study was classified based on precipitate in the highest test concentration where effects were observed. The status of the ecological effects data requirements for saflufenacil are listed in the attached table.



Although all of the data requirements for saflufenacil are fulfilled, it is important to note that as a result of the new CFR 40 Part 158 data requirements, avian acute oral data are now required for one passerine species in addition to either a waterfowl or upland game species for all new federal actions including Section 3 new chemical registrations. Avian oral toxicity data were not submitted for a passerine species exposed to saflufenacil; however, the available acute oral toxicity data for mallard duck and bobwhite quail, when compared to estimated environmental concentrations of saflufenacil, indicate that LOCs are not exceeded for birds on an acute basis. EFED acknowledges that the acute oral passerine study was not originally identified as a data gap when the initial registration package was screened for completeness; at that time, there was no Divisional policy on guidance for requesting acute oral passerine data. Currently, EFED policy requires that the lack of acceptable passerine data be listed as a data gap. However, given the timing of the EFED policy and the lack of observed effects at the highest saflufenacil treatment levels for other tested bird species, EFED recommends that the registration decision not be delayed based on the passerine data gap. If new uses of saflufenacil are proposed in the future, EFED would require that a passerine study protocol be submitted to the Agency prior to initiation of the study.

Summary of Ecological Effects Data Reviews for Saflufenacil ¹					
Guideline	Data Requirement	Formulation or Metabolite	MRID	Study Classification	Fulfills Data Requirements?
850.2100 (71-1)	Avian Acute Oral Toxicity Test	BAS 800 H BAS 800 H	47127911 47127912	Acceptable Acceptable	Yes ²
850.2200 (71-2)	Avian Dietary Toxicity Test	BAS 800 H BAS 800 H	47127913 47127914	Acceptable Acceptable	Yes
850.2300 (71-4)	Avian Reproduction Test	BAS 800 H BAS 800 H	47699904 ³ 47127916	Acceptable Acceptable	Yes
850.1075 (72-1)	Freshwater Fish Acute Toxicity Test	BAS 800 H BAS 800 H BAS 781 02H	47127904 47127905 47560401	Acceptable Acceptable Acceptable	Yes
850.1010 (72-2)	Aquatic Invertebrate Acute Toxicity Test, Freshwater Daphnids	BAS 800 H BAS 781 02H	47127901 47560402	Acceptable Acceptable	Yes
850.1075 (72-3)	Estuarine/Marine Fish Acute Toxicity Test	BAS 800 H	47127906	Acceptable	Yes
850.1025 (72-3(b))	Oyster Acute Toxicity Test (Shell Deposition)	BAS 800 H	47127902	Acceptable	Yes
850.1035 (72-3(c))	Mysid Acute Toxicity Test	BAS 800 H M07	47127903 47560303	Acceptable Acceptable	Yes
850.1400 (72-4)	Fish Early-Life Stage Toxicity Test	BAS 800 H	47127908	Acceptable	Yes
850.1300 (72-4)	Daphnid Chronic Toxicity Test	BAS 800 H	47127907	Acceptable	Yes
NA	Midge Chronic Toxicity in Spiked Water System	BAS 800 H	47127910	Supplemental ⁴	NA
850.5400	Algal Toxicity	BAS 800 H	47127923	Acceptable	Yes

(123-2)	(Tier II)	BAS 800 H BAS 800 H BAS 800 H M07 M08 BAS 781 02H	47127924 47127925 47127926 47560301 47560305 47560403	Acceptable Acceptable Acceptable Acceptable Supplemental ⁵ Acceptable	
850.4400 (123-2)	Aquatic Plant Toxicity Test Using <i>Lemna</i> spp.	BAS 800 H BAS 781 02H M07 M08	47127922 47560404 47560302 47560306	Acceptable Acceptable Acceptable Acceptable	Yes
850.3020 (141-1)	Honey Bee Acute Contact Toxicity	BAS 800 H BAS 800 01H	47127917 47445903	Acceptable Acceptable/Supplemental ⁶	Yes
850.6200	Acute Earthworm Toxicity	BAS 800 H M08	47127927 47560307	Acceptable Acceptable	Yes
850.4100 850.4150	Terrestrial Plant Seedling Emergence and Vegetative Vigor	BAS 800 01H BAS 800 01H BAS 800 02H BAS 800 02H M07 M08	47127919 47127921 47127918 47127920 47560304 47560308	Acceptable Acceptable Acceptable Acceptable Acceptable Acceptable	Yes
NA	Acute Toxicity to Predaceous Mite (<i>Typhlodromus pyri</i>)	BAS 781 02H BAS 800 01H	47523902 47430803	Supplemental ⁴ Supplemental ⁴	NA
NA	Acute Toxicity to Parasitoid Wasp (<i>Aphidius rhopalosiphii</i>)	BAS 781 02H BAS 800 01H	47523901 47523804	Supplemental ⁴ Supplemental ⁴	NA
NA	Soil Microflora Carbon Transformation Test	BAS 800 01H	47430801	Supplemental ⁴	NA
NA	Soil Microflora Nitrogen Transformation Test	BAS 800 01H	47430802	Supplemental ⁴	NA

¹ Data are available for technical grade saflufenacil (BAS 800 H), formulated products (BAS 781 02H, BAS 800 01H, BAS 800 02H), and metabolites (M07 and M08).

² EFED policy requires that the lack of acute oral passerine data be listed as a data gap; however given the timing of the policy and the lack of observed effects to other tested bird species, EFED recommends that the registration decision not be delayed based on this data gap.

³ MRID 47699904 replaces MRID 47127915 as an updated version of the Bobwhite quail reproduction study.

⁴ Non-guideline study.

⁵ Precipitate in highest test concentration where effects were observed.

⁶ The acute contact portion of the submitted honey bee study with BAS 800 01H is classified as "Acceptable"; the acute oral portion of the study is classified as "Supplemental" because acute oral honey bee tests are non-guideline studies.